DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
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Maitland, Florida 32751

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93776d

VIA CERTIFIED MAIL

WARNING LETTER

FLA-03-18

December 18, 2002

Jacqueline C. Butler, President
Greater Miami Caterers Inc.
4001 NW 31st Avenue
Miami, Florida 33142

Dear Ms. Butler:

We inspected your firm, at the above address on September 4 and 5, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations ca use your ready-to-eat fish products, such as cooked Alaskan Pollock fillets, cooked Mahi Mahi fillets and tuna salad, to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In accordance with 21 CFR 123.6(g), your failure to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part renders your fish products adulterated within the meaning of Section 402(a)(4) of the Act. Accordingly, your ready-to-eat fish products are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You can find the Act, the seafood HACCP regulations, and the Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 through links in FDA's home page at http://www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However your firm's HACCP plan titled "Frozen Fish" for cooked fillets fails to include a critical control point at Finished Product Storage (after cooking) to control the food safety of pathogen growth

and toxin formation. You must have a HACCP plan that at a minimum lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan titled "FROZEN FISH" for cooked fillets lists a critical limit of [redacted] for [redacted] at the cooking step which is inadequate to control pathogen survival. Please see Table #A3 of the Fish & Fisheries Hazards & Controls Guidance: Third Edition for acceptable time/temperature combinations.

We note that while the cook meets the requirements of the food code of 145°F for 15 seconds, wherein the target organism is Salmonella; FDA's guidance targets Listeria.

2. You must have a HACCP plan that, at a minimum, lists the monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for tuna salad lists a monitoring frequency of three times daily at the Finished Product Storage critical control point that is not adequate to control pathogen growth and toxin formation.

For finished product refrigerated storage of cooked ready-to-eat products, such as tuna salad, refer to Chapter 12 of the FDA Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001. For raw material, in-process, or finished product refrigerated storage, the FDA recommends continuous monitoring. The continuous monitoring can be accomplished through use of a digital time/temperature data logger, a recorder thermometer, or an alarm to monitor for high temperature 24 hours a day.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for ready-to-eat tuna salad at the Finished Product Storage critical control point to control the hazard of pathogen growth and toxin formation is not appropriate, as the corrective action fails to address the disposition of any product that is exposed to a critical limit deviation.

4. You must adequately monitor sanitation conditions and practices during processing with sufficient frequency to comply with 21 CFR 123.11(b). However, your firm did not adequately monitor maintenance of hand washing, hand sanitizing, and toilet facilities and exclusion of pests from the food plant as follows:

Hand washing facilities lacked hot water in the restroom and kitchen preparation area [21 CFR 123.11(b)(4)].

Live flies were observed in the kitchen preparation area. Dead cockroaches were observed in the receiving area and restroom [21 CFR 123.11(b)(8)].

5. You must maintain sanitation control records that document monitoring and corrections of sanitation conditions and practices during processing to comply with 21CFR 123.11(c). Although your firm manufactures ready-to-eat products such as tuna salad and cooked fish fillets, no such sanitation control records were maintained..

We previously sent an Untitled Letter dated November 17, 2000 addressed to your Vice President, John J. Olmo, which listed the failure to maintain sanitation control records. We do not have a record of any response to this letter. We acknowledge Mr. Olmo's statements during our current inspection promising correction action and a written response. However, we have not received any written response addressing any corrections.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as revised HACCP plans and completed sanitation control records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Shari J. Hromyak, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Hromyak at (407) 475-4730.

Sincerely,

Emma R. Singleton
Director, Florida District